908 KAR 1:340. Narcotic treatment programs.

RELATES TO: KRS 218A.180, Chapter 222, 315.020, 42 C.F.R. Part 8

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 222.231, 42 C.F.R. Part 8, EO 2004-726

NECESSITY, FUNCTION, AND CONFORMITY: EO 2004-726, effective July 9, 2004, reorganized the Cabinet for Health Services and Families and placed the Department for Behavioral Health, Developmental and Intellectual Disabilities within the cabinet. KRS 194A.050 and 222.231 authorize the Cabinet for Health and Family Services to establish guidelines and provide for the systematic evaluation of effectiveness of narcotic treatment programs. This administrative regulation establishes the State Narcotic Authority with the Behavioral Health, Developmental and Intellectual Disabilities, and establishes licensure and operations requirements for narcotic treatment programs.

Section 1. Definitions. (1) "Administrative detoxification" means the detoxification from the approved controlled substance for the safety and well being of the client, other clients, and staff of the narcotic treatment program.

(2) "Approved controlled substance" means the drugs methadone except for powdered methadone, or ORLAAM used in the treatment of narcotic addiction.

(3) "CHFS" or cabinet" means the Cabinet for Health and Family".

(4) "Client" means any individual who receives a controlled substance for the purpose of maintenance or detoxification in an NTP.

(5) "CSAT means the Center for Substance Abuse Treatment.

(6) DEA" means the Drug Enforcement Administration.

(7) "Dose" means a one (1) day quantity of an approved controlled substance, administered on site, in not less than one (1) fluid ounce of an oral solution, formulated to minimize misuse by injection.

(8) "Drug screening" means the process by which a program determines the presence or the absence of drugs in the body fluids.

(9) "Main program" means the location where all administrative and medical information related to the narcotic treatment program is retained for the purpose of on-site reviews by federal agencies or the state narcotic authority.

(10) "Medication station" means any dosing location that obtains its drug supply from the main program site and retains all records (except dosing, urine screens) at the main location.

(11) "Narcotic detoxification program" means a program using approved controlled substances in continually reducing dosages over a period of time for the purpose of relieving or reducing withdrawal symptoms.

(12) "Narcotic maintenance" means a treatment procedure using an approved controlled substance over a period of time to relieve withdrawal symptoms, reduce narcotic craving, and permit normal functioning so that, in combination with rehabilitation services, clients can develop a productive lifestyle.

(13) "Narcotic treatment program" or "NTP" means a substance abuse program using approved controlled substances and offering a range of treatment procedures and services for the rehabilitation of persons dependent on opium, morphine, heroin or any derivative or synthetic drug of that group.

(14) "ORLAAM" means a brand of levomethadyl acetate hydrochloride; levo-alpha-acetylmethadol hydrochloride.

(15) "Phase treatment" means the client's progress through treatment in a graduated sequence system.

(16) "Program sponsor" means a person or representative of an individual or entity who assumes responsibilities for the operation of a narcotic treatment program and for the on-site conduct of all employees, and other persons providing services, and ensures that the program is operated in compliance with this administrative regulation.

(17) "Proposed program" means an individual or entity in the process of seeking a narcotic treatment license.

(18) "Public health director" means the director of the local public health department.

(19) "SNA" means the State Narcotic Authority.

(20) "Take-home dose" means a quantity of an approved controlled substance which the client is eligible to take off site.

(21) "Voluntary detoxification" means a client requested, physician supervised withdrawal from the approved controlled substance.

Section 2. State Narcotic Authority. The SNA shall be the Department for Behavioral Health, Developmental and Intellectual Disabilities.

Section 3. Ordering of an Approved Controlled Substance. Programs shall order approved controlled substances from the manufacturer by submitting the Federal Form 222. The program sponsor or designee shall complete Form 222.

Section 4. Application to Operate a NTP. (1) A proposed program desiring to operate a NTP shall meet the requirements of this administrative regulation, and shall be licensed in accordance with KRS 222.231(12) and 908 KAR 1:370 prior to application.

(2) The proposed program shall submit each staff member's, including the program sponsor, administrator, and all other personnel, profile and resume of educational and professional experience, including Social Security numbers and date of birth.

(a) If the program is a corporation or partnership, the application shall list all partners' and members' names, addresses, dates of birth, and Social Security numbers.

(b) Failure to provide this information shall disqualify the application for further review.

(3) The proposed program shall submit or cause to be submitted on its behalf to the SNA a written protocol which shall serve as an application for licensure by the SNA. This protocol shall include the following:

(a) A plan of operation;

(b) A description of the geographic area to be served by the program;

(c) Population and area to be served;

(d) The estimated number of persons, in the described area, addicted to heroin or other morphine-like drugs and an explanation of the basis of the estimate;

(e) The estimated number of persons in the described area addicted to heroin or other morphine-like drugs presently under treatment in methadone and other treatment programs;

(f) The number of patients in narcotic treatment, projected rate of intake, and factors controlling projected intake;

(g) Program goal;

(h) Plan for evaluation;

(i) Memoranda of agreement which reflect supportive services from the administrative head of the following agencies:

1. Hospitals;

2. Local law enforcement including jails;

3. Community behavioral health and developmental and intellectual disability agencies;

4. Private, for-profit alcohol and drug services and publicly funded alcohol and drug services;

5. Department of Vocational Rehabilitation Services; and
6. Private, for-profit mental health counseling services;
(j) Client identification system;
(k) System to prevent client's multiple program registration;
(l) Organizational chart which includes the persons responsible for the program;
(m) First year budget, which list available, pending, or projected funds;
(n) Copies of letters verifying funding;
(o) Schedule of the amount of the client fees;
(p) Duties and responsibilities of each staff member and the relationship between the staffing pattern and the treatment goals;
(q) Duties and responsibilities of the medical director;
(r) Plan for delegation of the medical director's duties, if appropriate;
(s) Training and experience of counselors and therapists;
(t) Counselor and therapist caseload;
(u) Procedures and criteria for client selection;
(v) Program rules and instructions;
(w) Facility description;
(x) Initial dosage levels;
(y) Daily dosage levels;
(z) Operational procedures including the procedures to be used in inventory maintenance and daily dosing schedules;
(aa) Procedures, or documented efforts made, which provide for cooperation with local jails and hospitals for either withdrawal or maintenance while in custody or hospitalized in the event of client incarceration or hospitalization;
(bb) Procedures in the event of state or national or manmade emergency or disaster.
(cc) Urinalysis procedures which utilize random selection or unannounced collection;
(dd) Procedures for scheduled termination, voluntary termination, and involuntary termination for cause, including reasons for termination for cause;
(ee) Fair hearing procedures for client grievances;
(ff) Copies of all forms developed and to be used by the proposed NTP;
(gg) Facility address and dimensions;
(hh) Amount of space devoted to methadone treatment, including waiting, counseling, dispensing, and storage areas;
(ii) Days and hours of dispensing;
(jj) Days and hours of other program services;
(kk) Type of services provided and the hours of use, if the facility is also used for purposes other than narcotic treatment; and
(ll) Diagram of the facility housing the NTP and an accompanying narrative which describes client flow. The diagram and narrative shall specify:
1. Waiting areas;
2. Office space;
3. Dispensing area;
4. Urine collection locations;
5. Record storage area;
6. Parking or transportation access; and
7. The relation of the services to the facility diagram.
(4) A protocol proposing a new program or a complete revision of the protocol of an approved program shall be submitted to the SNA.
(5) The proposed program shall submit written policies and procedures in accordance with Sec-

tions 6, 7, 8, 9, 10, 11, 12, 13, 14 and 16 of this administrative regulation.

Section 5. SNA Application Review Process. (1) The SNA shall review the application materials within thirty (30) working days for the following:

(a) Criminal convictions by all individuals or entities involved with the proposed program within the past five (5) years, including violations of controlled substance laws and administrative regulations;

(b) Suspension or revocation of any CSAT, DEA, state narcotic licenses, or professional licenses in the past five (5) years of any staff member including the medical director, registered nurses, licensed practical nurses and registered pharmacist; and

(c) The written monitoring reports and compliance reports of other NTPs currently operated by the applicant or by any corporation or partnership with whom the applicant has been associated in the past five (5) years. These reports shall be obtained from the DEA and CSAT agents, medical licensing boards, pharmacy licensing boards, nursing licensing boards, and from other SNAs.

(2) The SNA shall not grant an application to operate a NTP to any applicant that has employed staff or, if applicant is a corporation or partnership, any officer of the corporation or member of the partnership who was convicted of a misdemeanor related to controlled substances laws or any felony within the last five (5) years.

(3) The SNA shall work in collaboration with the DEA and CSAT in reviewing the proposed application. Before any narcotic license shall be issued to the proposed program, the SNA, the DEA office, and the CSAT office shall all agree.

(4) The SNA shall conduct an on-site inspection to review the proposed program and interview the medical director, program sponsor and dosing staff.

(5) The SNA shall not approve any application for a NTP to any entity that poses a risk to the health and safety of the public based on a history of noncompliance with state and federal regulations as verified by the DEA or CSAT or state licensure agencies in states in which the entity currently legally operates.

(6) The SNA shall respond in writing, within ten (10) working days, to the proposed program upon receipt of all reports and documents from the applicant and all agencies involved.

(7) If the application to operate the NTP is approved the SNA shall, within thirty (30) working days of the completion of the review process:

(a) Issue a letter, pending receipt of federal approval, which shall indicate the approval to operate a NTP in Kentucky and shall include, the DEA license number, the CSAT license number, and the expiration date of the license to operate; and

(b) Assign a facility responsible for the distribution of the approved controlled substances to be used in the NTP.

(8) If the application to operate a NTP is not approved within thirty (30) working days, the SNA shall respond in writing citing the deficiencies, the requirements and time frames for taking corrective actions to make the program licensable.

(9) The proposed program shall provide a plan of correction for deficiencies cited within fifteen (15) working days from date of receipt of the written deficiencies.

Section 6. Organization and Administration Policies. (1) NTPs shall develop policies and procedures that include:

(a) Waiting list criteria;

(b) Criteria for the use of ORLAAM for clients needing or desiring take-home doses, but who do not meet eligibility requirements for take-home doses;

(c) Policies pertaining to the preparation and labeling of client doses which shall include:

1. The quantity of approved controlled substances that is indicated on the client's narcotic sheet

within the medical record;

2. Assurance that doses shall be labeled with the exact quantity of narcotic drug ordered;

3. Take-home doses shall be formulated in such a manner that shall reduce the likelihood of injecting the dose;

4. Policies that permit clients to know their dose level; and

5. Policies that shall provide for the packaging of take-home doses of the approved controlled substances in containers that meet the requirements of 15 U.S.C. 1471. The label of the doses shall include the name of the program, address and telephone number of the program, name of the controlled substance, name of the client, the name of the physician ordering the substance, and the quantity of the controlled substance, unless the client has requested in writing that the quantity of the substance not be revealed to them.

(2) The program policies shall indicate that the medical director or program physician at the individual NTP is in charge of all dose adjustments.

(3) The program policies shall indicate that dosing personnel do not alter client doses without the medical director or program physician's order.

(4) Verbal dosing orders shall be signed by the medical director or program physician within forty-eight (48) hours of the order's receipt.

(5) The medical record shall indicate any reason for dose changes and shall be signed by the medical director or program physician.

(6) Detoxification policies for voluntary and administrative detoxification shall be in compliance with 42 C.F.R. Part 8, i.e.: short-term (thirty (30) days or less), or long-term (more than thirty (30) days and as much as 180 days).

(7) Urine collection policies for drug screening purposes shall be developed to assure absence of falsification. Each sample shall be analyzed for the following drugs:

(a) Methadone;

(b) Cocaine;

(c) Opiates;

(d) Amphetamines;

(e) Barbiturates;

(f) Tetrahydrocannabinol;

(g) Benzodiazepines; and

(h) Any other drug(s) that has been determined by the NTP or the SNA to be abused in that program's locality or any other drugs that may have been abused by the client.

(8) NTPs shall have policies that prohibit procedures for offering a bounty, monetary or equipment or merchandise reward, or free services for individuals in exchange for recruitment of new clients into the program.

(9) NTPs shall assure compliance with the system of treatment phases outlined in Section 11 of this administrative regulation.

(10) NTPs shall develop quality assurance policies to assure that services provided are achieving beneficial effects for the clients using the services.

(11) Urine drug screens shall be reviewed by the treatment team monthly to determine client's reduction in the use of unauthorized medications.

(12) Controlled substance medications shall be considered unapproved usage if they are being used by the client without a valid prescription.

(13) A valid urine drug screen negative for the approved controlled substances, with the exception of ORLAAM, allowed to be used in the NTP shall be considered positive for unauthorized drug use.

(14) The NTP shall assure that urine drug screens are not used as the sole criteria for dismissing clients from the program.

(15) NTPs shall develop quality assurance procedures to determine the adequacy of the NTP's organization and service delivery. The assessment shall:

(a) Examine the content of the NTP's organizational and administrative structure and shall assess the following:

1. Availability of counseling services;
2. Availability of physical health services to clients;
3. Vocational training available to clients;
4. Legal assistance or referral, if indicated for the client;
5. Americans With Disabilities Act (ADA) defined accessibility in the on-site programs to the clients;
6. Quality assurance of the program services; and
7. Continuity of services and care.

(b) Be reviewed semiannually by the clinical supervisor, medical director, program sponsor, and the dosing nurse supervisor;

(c) Evaluate the following:

1. Appropriateness of the services delivered;
2. Completeness of documentation in client records;
3. Quality of and participation in staff training programs; and
4. Status of licenses and certification documents.

(16) All NTPs shall be open for dosing services seven (7) days a week with the optional exception of the following holidays:

(a) New Years Day, January 1;
(b) Presidents Day;
(c) Martin Luther King Day;
(d) Easter Sunday;
(e) Memorial Day, last Monday in May;
(f) Independence Day, July 4;
(g) Labor Day, first Monday in September;
(h) Thanksgiving Day, fourth Thursday in November; and
(i) Christmas Day, December 25.

Section 7. Personnel Policies. (1) The NTP shall have a program sponsor who shall:

(a) Assure that KRS 222.231, 908 KAR 1:370, 42 C.F.R. Part 8,, KRS Chapter 218A, 902 KAR 55:010 to 55:095 and this administrative regulation, are followed by the NTP;

(b) Have two (2) years documented experience in the treatment of addictions. The program sponsor shall be certified by the Board of Certification of Alcohol and Drug Counselors, or a physician, nurse, physician assistant, pharmacist, or nurse practitioner certified by the respective licensing subspecialty, or shall have a minimum of a masters degree in the field of addictions or related field; and

(c) Assure that clients:

1. Receive and sign written information describing all facets of the program in a manner that the client understands;
2. Have had the contents of the "Consent to Treatment with an Approved Narcotic Drug", Form FDA 2635 (7/93), communicated to them and voluntarily sign the consent to treatment;
3. Under eighteen (18) years of age, have parents or legal guardians of nonemancipated minors sign the consent to treatment;
4. Receive information on communicable diseases at admission, readmission, and at six (6) month intervals for the first two (2) years of treatment, and as indicated clinically after two (2) years. Communicable diseases shall include tuberculosis, hepatitis, sexually transmitted diseases,

and HIV/AIDS; and

5. Receive HIV/AIDS pretest, posttest counseling, and provide for voluntary HIV testing at admission or when clinically indicated thereafter.

(2) The program sponsor shall assure:

(a) That professional staff in the NTP shall maintain current credentials and that professional skills pertinent to their job descriptions shall be updated annually;

(b) That the laboratory performing the testing required under this administrative regulation is approved by the SNA, is certified by the Health Care Financing Administration as a CLIA (Clinical Laboratory Improvement Act-1988) certified laboratory, has a protocol in place that assures the integrity of the chain of custody for all urine drug tests, and an assurance that the initial test and confirmatory tests for drugs tested on behalf of the program meets the following standards;

1. Marijuana metabolites - initial screen 50ng/ml, confirmation test 15ng/ml;

2. Cocaine metabolites - initial screen 300ng/ml, confirmation test 150ng/ml;

3. Opiates metabolites - initial screen 300ng/ml, confirmation test 300ng/ml;

4. Amphetamines - initial screen 1000ng/ml, confirmation test of amphetamine 500ng/ml, and methamphetamine confirmation test 500ng/ml;

5. Barbiturates - initial screen 300ng/ml, confirmation test 300ng/ml; and

6. Benzodiazepines - initial screen 300ng/ml, confirmation test 300ng/ml.

(c) That drug test results shall not be used as the sole criteria for administratively detoxifying a client from the NTP;

(d) That when drug testing results are used, presumptive laboratory results shall be distinguished from results that are definitive;

(e) That urine samples used for drug screening purposes shall be handled in a manner that ensures client confidentiality;

(f) That client attendance shall not be revealed to any person or agency without the specific written authorization of the client, or a valid court order.

(3) NTPs shall have a medical director who shall:

(a) Be licensed by the Commonwealth of Kentucky to practice medicine within the Commonwealth and function autonomously within the NTP free from any protocol imposed by any NTP, sponsor, or any other entity except under the guidelines imposed by 42 C.F.R. Part 8 and this administrative regulation; and

(b) Be a board eligible psychiatrist licensed to practice in Kentucky and have three (3) years documented experience in the provision of services to persons who are addicted to alcohol or other drugs; or

(c) Be a physician licensed to practice in Kentucky and certified as an addictionologist by the American Society of Addiction Medicine; and

(d) Be responsible for dosing staff in the NTP and shall be responsible for the NTPs adherence to 42 C.F.R. Part 8, KRS Chapter 218A, 902 KAR 55:010 to 55:095, 908 KAR 1:370 and this administrative regulation.

(4) NTPs may have a program physician who shall:

(a) Be licensed by the Commonwealth of Kentucky to practice medicine within the Commonwealth and function autonomously within the NTP free from any protocol imposed by any NTP, sponsor, or any other entity except under the guidelines imposed by 42 C.F.R. Part 8 and this administrative regulation; and

(b) Be a board eligible psychiatrist licensed to practice in Kentucky and have three (3) years documented experience in the provision of services to persons who are addicted to alcohol or other drugs; or

(c) Be a physician licensed to practice in Kentucky and certified as an addictionologist by the American Society of Addiction Medicine; and

(d) Be responsible for dosing staff in the NTP and shall be responsible for the NTPs adherence to 42 C.F.R. Part 8, KRS Chapter 218A, 902 KAR 55:010 to 55:095, 908 KAR 1:370 and this administrative regulation.

(5) The medical director may be the program physician.

(6) There shall be one (1) medical director or program physician on staff for every 300 clients, or fraction thereof, enrolled in a NTP.

(7) The responsibilities of the medical director or program physician(s) shall include:

(a) Assuring there is evidence of physiologic dependence on narcotics for all clients admitted to the NTP;

(b) Assuring a history of addiction, or that any exceptions to admissions criteria are approved by the SNA and documented in the client's record before the first dose is administered;

(c) Assuring that appropriate medical histories and physical examinations have been performed before the first dose shall be administered;

(d) Assuring that appropriate laboratory studies have been performed and have a documented review by the medical director or program physician;

(e) Documenting, signing, or countersigning all medical orders, within forty-eight (48) hours, that include the first dose of narcotic drug or other approved medications;

(f) Documenting, signing, or countersigning all subsequent medication orders within forty-eight (48) hours, including dose increases and decreases, changes in frequency of take-home doses, emergency situations, or special circumstances;

(g) Assuring that information on all communicable diseases is communicated to all clients as required; and

(h) Assuring that a review and cosignatures of all telephone or other verbal orders are documented within forty-eight (48) hours of the order.

(8) The medical director or program physician at the NTP shall:

(a) Supervise clinical staff responsible for preparation and administering of the approved controlled substances; and

(b) Assure compliance with program procedures and administrative regulations;

(9) The medical director or program physician shall order all doses, all increases or decreases of doses of medications or other approved drugs for the client, through the licensed NTP.

(10) Any verbal orders shall be given to nursing or pharmacy staff and shall be cosigned by the medical director or program physician within forty-eight (48) hours of the order’s receipt.

(11) The medical director or program physician shall review all laboratory testing results required by the CSAT, SNA, and testing indicated by the client's clinical record. Any specific additional laboratory testing shall be ordered by the medical director or program physician.

(12) The medical director or program physician, in determining the client’s take-home medications, shall take into consideration the items addressed in 42 C.F.R. Part 8 and shall comply with Sections 10, 11, 12, 13 and 16 of this administrative regulation.

(13) NTPs shall provide dosing staff in sufficient numbers to meet the needs of the clients during dosing hours. Dosing staff shall:

(a) Hold a license as a registered nurse, licensed practical nurse, or pharmacist; and

(b) Not be dually assigned as counselors.

(c) Dosing physicians and pharmacists shall follow KRS 218A.180 related to labeling if preparing doses to be taken outside the program site.

(14) Programs shall provide counselors who shall have, at a minimum, a bachelors degree in a human services related field and an alcohol and drug counselor certification from the Kentucky Board of Alcohol and Drug Counselors or be actively engaged in the certification process.

(15) There shall be one (1) counselor for every forty (40) clients in the program.

Section 8. Physical Plant. (1) The building used for the NTP shall meet requirements in 21 C.F.R. 1301.74(j) and shall have space for the following operations:

(a) The waiting area shall be large enough to accommodate the clients arriving for services.

(b) The waiting area shall be separated from the dosing area to permit each client privacy and confidentiality at the time of dosing.

(c) The dosing area shall be clean and sanitary, shall accommodate the dosing staff, and shall contain the following:

1. A stainless steel sink;

2. Hot and cold running water;

3. A refrigerator for dosing supplies; and

4. Pill-counting trays if tablets are being used.

(2) Security and floor plan of the dosing area may be unique to each program, except shall conform to the requirements in 21 C.F.R. 1301.72.

(3) The NTP shall make arrangements for the facility to have two (2) restrooms which shall be handicapped accessible.

(4) The NTP shall assure that restrooms available to clients to provide urine specimens are secure, private, clean, and sanitary.

(5) The physical plant shall meet building, fire, safety, and health standards specified by state and local government laws and regulations.

(6) The physical plant shall be secured by a local security company approved by the DEA and the SNA.

(7) There shall be a minimum of two (2) panic buttons or similar devices for each NTP, one (1) in the reception area, and one (1) in the dosing area.

(8) There shall be a telephone with an outside line accessible in the dosing area.

(9) Internal security may be unique to each NTP and shall meet the requirements of 21 C.F.R. 1301.74(b), (h), (i), (j), (k); 1301.91; 1301.92 and shall be installed only after consultation with the DEA Office and the SNA.

(10) Parking space at the clinic site shall be adequate to accommodate the maximum number of clients expected to be at the clinic site at one (1) time or have specific appointment schedules to prevent the influx of clients that would be disruptive or unsafe to the surrounding community.

(11) The NTP shall comply with all local zoning and ordinance laws and requirements.

Section 9. Security and Control. (1) The security and control segment of the NTP's assessment procedure shall be conducted quarterly by the program sponsor and dosing nurse supervisor or pharmacist who shall assure that the requirements of 42 C.F.R. Part 8 are met. Other items to be evaluated shall include:

(a) Security of the narcotic safe and the building perimeter shall be checked with the contracted security company at the facility location, quarterly. The security company may choose to test the system by telephone.

(b) The safe shall be locked at all times while staff are not obtaining or restocking controlled substances.

(c) Inventory reconciliation shall be conducted, at a minimum of quarterly, and all reconciliation documents shall be retained by the program for five (5) years.

(d) Five (5) percent or more of any inventory discrepancies shall be reported to the SNA and the DEA offices within forty-eight (48) hours of reconciliation.

(e) Dosing personnel shall count all new bottles of narcotic tablets before removing any for client doses. Any discrepancies shall be reported to the SNA, to the DEA and CSAT, and the Department for Health Services' Office of Drug Control, using the DEA 1305.12 (12/85) "Report of Theft or Loss of Controlled Substances" form, within forty-eight (48) hours of the event.

(f) A system shall be devised to assure the NTP completes the DEA biennial inventory of narcotic drugs on hand.

(g) Order forms for controlled substances, the dosing records, and inventory reconciliation records shall conform to 42 C.F.R. Part 8 and shall be maintained in a locked, secured area separate from the storage site of the controlled substances.

(2) Utilization and effectiveness of delivered services shall be reviewed by the program sponsor and medical director annually for the following:

(a) Treatment slot utilization and cost per slot;

(b) Staff-to-client ratio;

(c) Cost per counseling session; and

(d) Cost per client for other program services.

(3) NTPs shall maintain written policies to assure the confidentiality of all client records.

(4) Quarterly, the program sponsor shall review a ten (10) percent random sample of client records for the following information and assurances:

(a) Client signed the "Consent to Treatment with an Approved Narcotic Drug," Form FDA 2635 (7/93);

(b) Client signed a release of information form, developed by the NTP, which shall include:

1. Specific type of confidential information to be obtained or released; and

2. Specific dates that the release is to cover.

(c) If the program sponsor serves as a counselor then the medical director shall review ten (10) percent of the program sponsor's client records for the same information and assurances as cited above in paragraphs (a), (b)1 and 2 of this subsection.

(5) The NTP shall retain a copy of internal assessment documents on file, which shall be available for review by regulatory agencies for five (5) years.

(6) The NTP shall participate in the data collection system as addressed in 908 KAR 1:300.

Section 10. Admission and Readmission Policies. (1) The admitting physician for the NTP shall comply with the admission requirements of 42 C.F.R. Part 8.

(2) Exceptions to the admission requirements shall be those cited in 42 C.F.R. Part 8. Programs shall adhere to the following for pregnant clients: In order for a NTP to admit or continue to treat a client who is pregnant the medical director or program physician shall first determine and document in the client's record the following:

(a) The client is medically able to participate in the program.

(b) If the medical director or program physician does not accept the responsibility for providing prenatal care for the term of the client's pregnancy, the medical director or program physician shall refer the client to a primary care physician who practices obstetrics or an obstetrician and shall inform the attending physician of the client's participation in the NTP.

(c) If a pregnant client, the medical director or program physician shall ensure that appropriate arrangements have been made for the addiction-related medical care of both the client and the child following the birth of the child.

(d) Maintenance treatment dosage levels of pregnant clients shall be maintained at the lowest possible dosage level.

(e) The program shall ensure that the following services are available for pregnant addicts and are a part of the treatment plan:

1. The medical director or program physician shall notify the pregnant client's primary care physician of any changes in the client's treatment;

2. Nutritional counseling;

3. Parenting training including newborn care, handling, health, and safety; and

4. Weekly full drug screen urinalysis;

(3) When a client applies for admission to a NTP the client shall be required to sign a release of information that authorizes a program to release or solicit information regarding the client's status in any other substance abuse program.

(4) A client who has received treatment and later voluntarily detoxified may be readmitted to a NTP without evidence to support findings of current physiologic dependence, up to two (2) years after discharge if the NTP attended is able to document prior treatment of six (6) months or more, and the admitting medical director or program physician finds readmission to the NTP to be medically justified.

(5) If a client seeks readmission to a NTP after being administratively detoxified and the medical director or program physician finds readmission to the NTP medically justified, the medical director or program physician shall document such justification in the client's medical record.

Section 11. Treatment Protocol. NTPs shall comply with the following treatment phase system to achieve the goals of reduced health problems, reduced criminal activity, increased productivity, stabilization of family life and eventual drug free living.

(1) Entry phase. The first ninety (90) days of treatment all clients shall adhere to the following:

(a) Clients shall be dosed with methadone seven (7) days at the clinic site.

(b) Clients shall be provided weekly counseling sessions to support the implementation of their treatment plan.

(c) Clients shall be provided HIV/AIDS education and provided or referred for HIV pretest counseling and voluntary HIV testing.

(d) Clients shall be oriented to appropriate twelve (12) step programs such as narcotics anonymous or alcoholics anonymous.

(e) During the entry phase the client shall provide an observed urine sample one (1) time per week on a random basis.

(f) There shall be documentation in the client record that treatment plans shall be reviewed and updated a minimum of every thirty (30) days for three (3) months, every ninety (90) days thereafter.

(g) The medical director or program physician shall sign the treatment plan.

(2) Phase one (1). In order for a client to enter phase one (1) the client shall not have committed any program infractions (dirty urine screens, disruptive behavior at the clinic site, threats to staff or other clients, failure to attend scheduled dosing or counseling appointments) for ninety (90) consecutive days.

(a) Once the client enters phase one (1) the client shall attend clinic six (6) times each week for observed ingestion of methadone and shall be eligible to receive a one (1) day take-home dose of methadone.

(b) Clients shall be provided weekly counseling sessions to support the implementation of their treatment plan.

(c) The client shall provide an observed urine sample on a random basis at least weekly.

(d) Clients shall be encouraged to attend an appropriate twelve (12) step program.

(e) There shall be documentation in the client record that treatment plans shall be reviewed and updated every ninety (90) days. This documentation shall include a report on the client's progress in relation to his treatment plan.

(f) The medical director or program physician shall sign the treatment plan.

(3) Phase two (2). In order for the client to enter phase two (2) the client shall:

(a) Not have committed any program infractions (dirty urine screens, disruptive behavior at the clinic site, threats to staff or other clients, failure to attend scheduled dosing or counseling appointments) for 180 consecutive days;

(b) Be pursuing gainful employment or vocational training or attending school or be engaged in

volunteer work, or be attending parenting classes if they are a parent at home with children. Clients with disabilities or other circumstances which might prohibit this requirement may submit a written waiver request to the SNA justifying specific reasons for the request;

(c) Have a treatment plan to meet any special needs, including disabilities;

(d) Attend clinic five (5) times each week for observed ingestion of methadone and be eligible to receive up to two (2) days of take-home doses of methadone;

(e) Provide an observed urine sample randomly on a monthly basis, or more frequently if their treatment plan requires;

(f) Be provided monthly counseling sessions, or more frequently if their treatment plan requires;

(g) Be encouraged to attend appropriate self-help programs outside the clinic;

(h) Have documentation in the client record that treatment plans shall be reviewed and updated every ninety (90) days. This documentation shall include a report on the client's progress in relation to the treatment plan; and

(i) Have their treatment plan signed by the medical director or program physician.

(4) Phase three (3). In order for the client to enter phase three (3) the client shall:

(a) Not have committed any program infractions (dirty urine screens, disruptive behavior at the clinic site, threats to staff or other clients, failure to attend scheduled dosing or counseling appointments) for 270 consecutive days;

(b) Have met the same entry criteria requirements as noted in phase two (2);

(c) Attend clinic three (3) times each week for observed ingestion of methadone and be eligible to receive up to two (2) days of take-home doses of methadone;

(d) Provide an observed urine sample on a random basis, monthly, or more frequently if their treatment plan requires;

(e) Be provided monthly counseling sessions, or more frequently if their treatment plan requires;

(f) Be encouraged to attend appropriate self-help groups outside clinic;

(g) Have documentation in the client record that treatment plans shall be reviewed and updated every ninety (90) days. This documentation shall include a report on the client's progress in relation to their treatment plan; and

(h) Have their treatment plan signed by the medical director or program physician.

(5) Phase four (4). In order for the client to enter phase four (4), the client shall have successfully completed phase three (3) and adhered to the requirements of the maintenance treatment program for two (2) consecutive years.

(a) Clients shall be dosed at the clinic site two (2) days per week for observed ingestion of methadone and be eligible for up to three (3) take-home doses of methadone.

(b) The number of counseling sessions provided during this phase shall be based on the clinical judgement of the program physician and program staff.

(c) Requirements in the area of urine sample schedules, and treatment plan reviews remain the same as in subsection (4) of this section.

(d) Prior to successful completion of phase four (4), a plan shall be developed which shall assist the client toward a drug free treatment regimen for continued support.

(e) The medical director or program physician shall sign the treatment plan.

Section 12. Client Program Compliance. In order for a client to remain in a NTP and to successfully move through the treatment phases, clients shall be actively involved in the NTP by remaining in good standing at the clinic or risk being administratively detoxified. If a client has not complied with program policies:

(1) The client may be placed on a behavioral contract for a minimum of sixty (60) days during any individual program phase and shall lose all take-home dose privileges for sixty (60) days.

(2) If a client commits three (3) infractions, the medical director or program physician and staff may choose to move the client back in phases as part of the behavioral contract. The client shall lose all take-home privileges during the contract period.

(3) Following the commitment of any program infraction, the counseling staff shall assist the client in correcting the problem behavior and document this effort in the client's treatment plan.

(4) If the client continues to experience problems and breaks the behavioral contract, the client may be administratively detoxified based on the recommendation of the program physician and the program staff.

Section 13. Client Transfers. NTPs shall accept clients transferring from another program within the state, if:

(1) The NTP accepting a client voluntarily transferring from another NTP shall provide documentation that the client's medical record and reason for the transfer was sought from the client's previous NTP; and

(2) The client is in compliance with readmission policies for clients who have been administratively detoxified.

(3) In order for the client to transfer to another NTP, the following requirement shall be met:

(a) The NTP that client is leaving shall forward all relevant client records to the program where the client is transferring.

(b) The NTP shall provide documentation that the client's medical record and reason for the transfer was sought from the client's previous NTP and shall meet the admission criteria of this administrative regulation.

(c) Clients who are Kentucky residents and wish to transfer to another Kentucky-based program shall be reviewed by the new program’s admission program physician or medical director on an individual basis to determine their placement on the receiving program's client listing. The review shall determine the client's need, program placement availability, and the circumstances for the transfer request.

(d) Clients who are not Kentucky residents shall transfer to a Kentucky program as a new admission or "Entry Phase" as noted in this administrative regulation, Section 11(1) of this administrative regulation, unless other phase levels are approved by the SNA.

Section 14. Client Appeal Procedures. Decisions regarding a client's treatment by staff shall be subject to appeal by the client. Each NTP shall:

(1) Develop an appeal procedure that shall be approved by the SNA; and

(2) Have procedures that include a provision that a central file of all client appeals be maintained at the NTP for review by the SNA.

Section 15. Program Waiver Process. A NTP may make an application to the SNA in order to seek waivers from any requirement of this administrative regulation.

(1) This application for a waiver shall:

(a) Be in the form of a letter to the SNA;

(b) Identify the specific sections of this administrative regulation for which a waiver is being sought; and

(c) Give the rationale for the request.

(2) A copy of the waiver request and response shall become part of the client's permanent record.

(3) Applications for waiver requests shall be mailed to: Kentucky State Narcotic Authority Department for Behavioral Health, Developmental and Intellectual Disabilities,, 275 East Main Street, Frankfort, Kentucky 40621.

(4) The SNA shall respond, in writing, to the waiver request within fifteen (15) working days. The SNA shall provide written justification for any waiver request that has been denied.

Section 16. Take-home Doses. (1) Under emergency conditions a program may issue fourteen (14) consecutive days of take-home doses without notification of CSAT. The NTP shall notify the SNA and request, in writing, an exception to dosing procedures prior to administration of the first emergency dose. This request shall include:

(a) The number of take-home doses requested;

(b) The reason for the request; and

(c) The client's standing in program phases, adherence to program policies, and the total length of time the client has been enrolled at the NTP.

(2) The medical director or program physician may grant an exception to the criteria for take-home dosages for any of the following reasons subject to the limitations in this administrative regulation and written approval from the SNA which shall be filed in the client record:

(a) The client has a serious physical disability which would prevent frequent visits to the program facility.

(b) The client is subject to an exceptional circumstance such as acute illness, family crisis, or necessary travel, where hardship would result from requiring exact compliance with the step level schedule as noted in this administrative regulation. If a client must travel out of the program area, the medical director or program physician shall attempt to arrange for the client's daily dosage to be received at another program in lieu of increasing take-home dosages.

(c) The medical director or program physician shall not grant any exceptions during a calendar month which exceed three (3) exceptions or ten (10) percent of the number of patients enrolled in the program on the last day of the previous month, whichever is greater.

(d) The medical director or program physician shall document in the client's record the granting of any exception and the facts justifying the exception. Each program shall also maintain a separate record for all exceptions granted.

(e) The SNA shall not grant additional exceptions, except in cases of medical emergency or natural disaster, such as fire, flood, or earthquake.

(3) A NTP shall restrict a client's take-home dosage privileges by moving the client back at least one (1) step level on the schedule for take-home dosages if the client's urinalysis results disclose the unauthorized presence of methadone, cocaine, opiates, amphetamines, barbiturates, tetrahydrocannabinol, benzodiazepines, and any other drug(s) that has been determined by the NTP or SNA to be abused in that NTP's locality or any other drug(s) that may have been abused by the client twice or more in a sixty (60) day period.

(4) A NTP shall restrict a client's take-home dosage partially, by moving the client back on the take-home dosage schedule, if the medical director or program physician concludes that the client is no longer a suitable candidate or risk for take-home privileges as presently scheduled.

(5) A NTP shall revoke a client's take-home privileges for not less than thirty (30) days and shall require the client to ingest each dosage at the facility for any of the following reasons:

(a) The client's urinalysis discloses an absence of methadone, or methadone metabolite, and the medical director confirms the accuracy of such analysis. This shall not be applicable to clients whose daily dosage is twenty-five (25) milligrams or less.

(b) The client is discovered to be misusing methadone, as defined in paragraph (e)3 of this subsection.

(c) The client attempts to register in another NTP.

(d) The client alters or attempts to alter a urinalysis.

(e) The client is not satisfactorily adhering to the requirements of the NTP by the following:

1. The client has not complied with all the rules of the NTP.

2. There is indication that the client has repeatedly used drugs improperly.

3. There is indication, including appropriate urinalysis results, that the client is misusing methadone. Misuse of methadone includes sharing, giving away, selling, or trading one's methadone dosage, or not ingesting it in accordance with methadone maintenance treatment program rules.

4. There is indication that the client is selling, distributing, or otherwise involved with illicit drugs and their use.

5. The client is not participating in an educational, vocational, or home-making activity.

(6) A client whose take-home privileges were revoked or restricted may regain take-home privileges according to the following schedule:

(a) Phase one (1) by satisfactory adherence for at least thirty (30) days.

(b) Phase two (2) by satisfactory adherence for at least thirty (30) days after regaining phase one (1) privileges.

(c) Phase three (3) by satisfactory adherence for at least thirty (30) days after regaining phase two (2) privileges.

(d) Phase four (4) by satisfactory adherence for at least thirty (30) days after regaining phase three (3) privileges.

(e) This section shall not be used to circumvent the requirements of this administrative regulation. A client shall not be advanced to a phase level pursuant to this section unless he has previously been at that phase level after having satisfied the requirements of this administrative regulation.

(7) If a NTP fails to comply with the requirements in Sections 6, 7, 8, 9, 10, 11, 12, 13 or 16 of this administrative regulation, the SNA may order the NTP to suspend all or part of the take-home privileges for a period of thirty (30) days. The SNA shall notify the NTP in writing, prior to any suspension, indicating the reasons for the suspension:

(a) The NTP shall submit a plan of correction to the SNA within ten (10) days of receipt of the SNA notification.

(b) If the NTP does not make the corrections in the time specified, except has responded within the ten (10) day time period indicating circumstances which the SNA has approved, the SNA may extend the suspension for up to a second thirty (30) day period.

(c) If the NTP does not make the necessary corrections or does not submit an acceptable plan of correction with the SNA within the time frame specified in paragraph (a) of this subsection, the SNA shall suspend the NTP's take-home program until the necessary corrections have been made.

(d) If the NTP is determined by the SNA to not comply with Sections 6, 7, 8, 9, 11, 10, 11, 12, 13 or 16 of this administrative regulation and is serving clients who meet the requirements in Sections 10 and 11 of this administrative regulation, the SNA may restrict the NTP's take-home procedures to the provision of emergency take-homes according to the requirements of Section 16 of this administrative regulation. This restriction shall be in effect on a client-by-client basis until the NTP has taken corrective actions that bring the program into compliance with Sections 6, 7, 8, 9, 10, 11, 12, 13 and 16 of this administrative regulation.

(8) Maintenance treatment shall be discontinued within two (2) continuous years after the treatment is begun unless, based upon the clinical judgement of the medical director or program physician and staff which shall be recorded in the client's record by the medical director or program physician, the client's status indicates that the treatment should be continued for a longer period of time because discontinuance from treatment would lead to a return to illicit opiate abuse or dependence.

(9) Client status relative to continued maintenance treatment shall be reevaluated at least annually after two (2) continuous years of maintenance treatment and documented in the client's record by the medical director or program physician or maintenance treatment shall be terminated.

(10) Documentation of the justification for continued maintenance treatment required by this administrative regulation shall indicate the client's progress, or lack thereof, and future expectations as required by this administrative regulation.

(11) Each NTP shall submit a specific plan for a client's scheduled termination of maintenance treatment indicating a period of maintenance before the scheduled termination.

(12) The termination plan shall include dosage schedules, information on counseling, and any other patient support which will be provided during withdrawal.

(13) Scheduled withdrawal shall be under the immediate direction of the medical director or program physician and shall be individualized.

(14) A client may voluntarily terminate participation in a NTP even though termination may be against the advice of the NTP.

(15) If the medical director or program physician determines that the client's continued participation in the program creates a physically threatening situation for the staff or other clients, the client's participation may be terminated immediately.

(16) A client's participation in a NTP may be involuntarily terminated for cause.

(17) If a NTP utilizes disciplinary proceedings which include involuntary termination for cause, the program shall include in its protocol reasons and procedures for involuntarily terminating a client's participation in the program. The procedures shall provide for:

(a) Explanation to the client of when participation may be terminated for cause;

(b) Client notification of termination;

(c) Client's right to hearing; and

(d) Client's right to representation.

(18) If the NTP elects not to terminate for cause, the protocol shall state that clients shall not be involuntarily terminated for cause except as provided in subsection (15) of this section.

(19) Except as noted in subsection (15) of this section, either voluntary or involuntary termination shall take place over a period of time not less than fifteen (15) days, unless:

(a) The medical director or program physician deems it clinically necessary to terminate participation sooner and documents why in the client's record; or

(b) The client requests in writing a shorter termination period.

Section 17. Client Rights. The following shall apply:

(1) Clients shall have the right to voluntary detoxification from the NTP.

(2) The client rights shall be posted in conspicuous places in the facility.

(3) The client rights shall be signed by the individual client attesting the client rights have been explained in such a manner that they are understood. This signed copy shall be maintained in the client's permanent medical record.

(4) Decisions regarding a client's treatment by staff may be subject to appeal by the client.

(5) Each NTP shall develop an appeal procedure that shall be approved by the SNA and shall include the following:

(a) Each appeal procedure shall contain a detailed description of the NTP's pretermination fair hearing procedure. The appeal procedure shall provide that a client has a right to a pretermination fair hearing if involuntarily terminated from the program for cause if continued participation in the program does not create a physically threatening situation for staff or others clients. The procedure shall require:

1. Identification of reasons for termination, as stated in the program rules, which may include:

a. Polydrug abuse;

b. Diversion of methadone;

c. Violence or threat of violence to program staff or other clients in the program; or

d. Multiple registration.

2. Written notification to the client of pending termination, containing:

a. Reasons for termination; and

b. Explanation of right to pretermination fair hearing, which shall explain to the client that rights shall be exercised within forty-eight (48) hours of written notice.

3. Provision for continuance of client's treatment status pending decision upon hearing;

4. Explanation of the client's rights during the hearing to:

a. Be represented at the hearing by a person or attorney of their choice;

b. Call witnesses on their behalf, who need not be under oath; and

c. Examine witnesses presented by the NTP.

5. Release of medical information in the client's file to the client or the client's representative at least forty-eight (48) hours prior to the hearing;

a. Medical information requests by the client shall be in the form of a signed consent to release of information.

b. Medical information to be released to the client or client's representative shall be provided by the physician in charge of the client.

(b) The appeal procedure shall state whether the client is entitled to a hearing before a panel or before a single hearing officer. If the procedure states that the client is entitled to a hearing before a panel, a single hearing officer may not be substituted for the panel without the consent of the client. If a hearing before a panel, a majority vote of the panel shall be necessary to terminate a person from the NTP.

(c) The NTP shall select the hearing officer or panel from impartial persons not directly involved with the client's care.

(d) A hearing shall be scheduled within ten (10) working days from the time the client requests a hearing.

(e) Unless the program procedures require a higher standard of proof, a client's participation in a program shall be terminated for cause only after the hearing officer or panel finds by a preponderance of the evidence presented that the reason stated in the notice justifies termination.

(f) The hearing officer or panel shall render a decision not later than the fifth working day following the hearing. The NTP shall keep a permanent record of the proceeding. The permanent record of the proceedings may be a tape recording. The decision shall be made in writing and shall be based solely on the evidence presented at the hearing. The decision shall include a summary of the proceedings and the formal findings and conclusions of the hearing officer or panel.

1. A copy of the hearing decision shall be provided to the client.

2. Copies of all written materials, including all evidence introduced at the hearing, shall be retained for one (1) year.

(g) A client may appeal an adverse action of a hearing officer or panel by the following:

1. The client may appeal the decision by filing an appeal with the Office of the Secretary, Cabinet for Health and Family Services, 275 East Main Street, Frankfort, Kentucky 40621 within thirty (30) working days of the decision.

2. The hearing shall be conducted in accordance with the requirements of KRS Chapter 13B.

(6) All client appeals shall be maintained at the NTP for review by the SNA for two (2) years.

Section 18. Protocol for the Change of a NTP Location and the Protocol for Establishment of a Medication Station. The protocol shall be current, detailed, specific, and complete to permit evaluation by the SNA and to provide a basis for compliance inspections or surveys.

(1) If a NTP voluntarily decides to change its location or establish a medication station, the program shall notify, in writing, the DEA, CSAT, the SNA and the Office of the Inspector General within the cabinet within ninety (90) days of the proposed relocation. The written request to relocate shall include the following information:

(a) The reason for the relocation;
(b) The relocation site;
(c) The proposed date of the relocation;
(d) Indicate any program changes that may occur with the relocation; and
(e) If the NTP is within ninety (90) miles of the original site, the NTP shall provide the following:
1. Any dosing procedural changes; and
2. Any drug distribution problems which may occur due to the relocation.
(f) A medication station may be opened no closer than forty-five (45) miles and no further than ninety (90) miles to the main NTP.
1. The medication station shall obtain its supply of approved controlled substance from the stocks of the main NTP.
2. The medication station shall provide the following services:
a. Dosing; and
b. Urine screen collection.
3. The program sponsor shall develop a system to prevent clients from dosing at the main NTP and the medication station.
4. Any services provided at the medication station other than those listed above shall have prior approval by the CSAT and SNA.
(2) The CSAT, the DEA, and the SNA shall agree that the NTP may establish a medication station or relocate to the proposed relocation site. Written approval shall be forwarded to the NTP.
(3) If a NTP voluntarily decides to close its operation, it shall notify the SNA, the DEA, CSAT and the Office of the Inspector General within ninety (90) days before the planned closure of the program.

Section 19. Monitoring of NTPs. (1) The SNA shall monitor NTPs to assure the health and safety of program clients and the protection of the community at large. Monitoring visits shall be conducted annually, or more frequently if indicated. The SNA may:
(a) Discontinue all take-home doses of any approved controlled substance used in any NTP; or
(b) Discontinue the utilization of any drug approved for use in narcotic treatment programs.
(2) Focused, unannounced monitoring visits may be conducted more frequently and may occur in conjunction with the CSAT and the DEA.
(3) Monitoring shall include:
(a) Inspection of the NTP licensing status;
(b) Inspection of the status of all applicable staff licenses and certificates;
(c) Inspection of the status of the NTP's CSAT, DEA, and state licenses;
(d) Inspection of the NTP’s security which shall include:
1. Building security, perimeter and internal; and
2. Security of staff procedures in receipt of narcotic drug, storage of narcotic drug, and handling of the drug in preparation and dosing functions;
(e) Inspection of the records maintenance, the inventory control procedures, and the internal inventory reconciliation procedures;
(f) Inspection of the procedures the program has in place to reduce the likelihood of drug diversion by program clients and staff; and
(g) A random sample of doses prepared for administration may be pulled for quantitative analysis and the SNA shall submit to the program sponsor a receipt for any doses taken for analysis.
(4) Client records shall be reviewed for the following:
(a) Client signed consent to treatment with a controlled substance before the first dose was administered;
(b) Conformity with 42 C.F.R. Part 8 requirements for minimum medical evaluations;

(c) Conformity with 42 C.F.R. Part 8, Sections 6(7) and 11(1)(e), (2)(c), (3)(e), (4)(d) of this administrative regulation for urine drug screening requirements;

(d) Conformity with client record that when the urine drug screen is positive for use of unapproved drugs, or is negative for the approved controlled substance, the client is counseled and suitable therapeutic action is taken by the treatment team, and the client's take-home doses have been discontinued for thirty (30) days. Except, the urine drug screen shall not be used as the sole or primary reason for dismissing the client from the NTP; and

(e) Treatment plans have been developed and have been signed by the medical director or program physician in accordance with this administrative regulation;

(f) All physician orders for medications, doses, and dose changes and other treatments have been signed by the medical director or program physician within forty-eight (48) hours of the order's receipt;

(g) No medications are administered without the physician's orders;

(h) The SNA shall monitor for all other CSAT, DEA, or SNA administrative regulations; and

(i) Records shall be reviewed for compliance with all treatment phases and waiver requests and approvals.

Section 20. Penalties. Penalties may be issued by the SNA to NTPs that have violated CSAT and DEA requirements, and this administrative regulation as follows:

(1) If a monitoring visit reveals regulatory violations, the SNA shall, within ten (10) working days issue a written report, which also shall be submitted to the CSAT and DEA, with a time frame of thirty (30) days for the NTP to submit a plan of corrective action.

(2) If a plan of corrective action has been submitted within the thirty (30) days and is acceptable, the SNA shall notify the NTP in writing.

(3) A follow-up visit to verify that corrective action has been made may be performed by the SNA.

(4) If the NTP has not filed a plan of corrective action within thirty (30) days after receipt of the report, the NTP shall be notified that its license shall be suspended for a period not to exceed six (6) months or revoked.

(5) Upon notification of suspension or revocation, the NTP may appeal the suspension or revocation in accordance with Section 21 of this administrative regulation.

(6) The SNA shall immediately suspend or revoke any narcotic treatment license if there is an emergency affecting the health and safety of the client population or the community as a whole.

(7) The grounds which justify the immediate suspension or revocation of a license shall be as follows:

(a) Take-home doses that fall outside this administrative regulation without specific CSAT, DEA, or SNA approval prior to issuance of the take-home dose;

(b) The allowable difference between the labeled dosage of the approved controlled substance and the actual dosage as determined by a drug assay shall be the United States Pharmacopeia error rate;

(c) More than five (5) percent of the medical and dosing records reviewed are out of compliance with the administrative regulations;

(d) Discrepancies in the inventory reconciliation greater than five (5) percent;

(e) Continued dosing of clients prior to completion of the intake procedures, including physical exam, except under SNA approved circumstances;

(f) Evidence in the client's record that the physician is not in control of the client's treatment;

(g) Consistent dosing of clients before the consent to treatment with controlled substances has been signed by the client;

(h) Consistent failure to conduct the required urine drug screening procedures on all drugs

listed in Section 6(7) of this administrative regulation;

(i) Failure to comply with Section 8(5) of this administrative regulation; and

(j) Revocation of licensure.

(8) The SNA shall notify the CSAT monitor, DEA, and the Department for Health Services Office of Drug Control at the time revocation or suspension is taken in accordance with subsection (4) of this section.

(9) Except in cases of emergencies affecting the health and safety of the client population or the community as a whole, an appeal shall stay any decision to suspend or revoke a license to operate pending final decision of the secretary.

Section 21. Appeals. If the SNA takes action to deny, suspend, or revoke a NTP license, the SNA shall notify the NTP in writing stating the reasons for the adverse actions and the NTP's right to appeal.

(1) If the NTP believes an action by the SNA is unfair, without reason, or unwarranted, the NTP may appeal the action in writing to the Secretary, Cabinet for Health and Family Services, Fourth (4th) Floor, 275 East Main Street, Frankfort, Kentucky 40621, within fifteen (15) days after receipt of notice of action from the SNA.

(2) Upon receipt of the appeal, the secretary, or designee, shall notify the NTP in writing within fifteen (15) days of the time and place of the hearing. The secretary, or his designee, shall appoint a hearing officer to conduct the hearing in accordance with KRS Chapter 13B.

(3) The hearing officer shall have authority to issue subpoenas to compel the attendance of witnesses and the production of documents to be used as evidence in hearings held pursuant to this section.

(4) Based upon the record and upon the information obtained at the hearing, the hearing officer shall affirm or overturn the initial decision of the negative action. The decision of the hearing officer shall be final. The NTP shall be notified in writing of the decision of the hearing officer.

(5) If a NTP, whose license has been suspended or revoked pursuant to Section 20(6) and (7) of this administrative regulation, requests a hearing, the cabinet shall conduct the hearing within ten (10) working days of receipt of the request from the NTP. The hearing may be continued at the request of the NTP.

(a) The sole issue of the hearing shall be whether one (1) or more grounds for suspension or revocation create an immediate danger to the client population or the community as a whole.

(b) The cabinet shall render a decision within five (5) working days of the hearing. If a decision is not rendered within five (5) working days of the hearing, the NTP shall have its license returned and be allowed to operate pending action on other regulatory violations, if any.

(c) If the hearing officer decides within five (5) working days of the close of the hearing that one (1) or more of the grounds for suspension or revocation create an immediate danger to the client population or the community as a whole, the license of the NTP shall be suspended pending action of the cabinet to accept the plan of correction or revoke the license.

(6) If suspension or revocation of the license is upheld, the secretary's, or designee's, notification shall specify the date by which the NTP shall close.

(7) A NTP that continues to operate after the closing date established by the secretary shall be subject to legal action by the cabinet as provided by law.

Section 22. Material Incorporated by Reference. (1) The following material is hereby incorporate by reference:

(a) Consent to Treatment with an Approved Narcotic Drug form FDA 2635 (7/93);

(b) Report of Theft or Loss of Controlled Substances form DEA 1305.12 (12/85); and

(c) US Official Order Forms-Schedules I & II DEA form 222 (10/92) are hereby incorporated by

reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Behavioral Health, Developmental and Intellectual Disabilities, 275 East Main Street, Fourth Floor, Frankfort, Kentucky 40621, 8 a.m. through 4:30 p.m., Monday through Friday. (22 Ky.R. 2512; Am. 23 Ky.R. 449; eff. 8-21-1996; 25 Ky.R. 935; 1384; eff. 12-16-1998; 30 Ky.R. 1649; 1948; eff. 2-16-2004; TAm eff. 4-27-2016.)